

Food and Drug Administration, HHS

§ 25.5

the agency, if one has been prepared, of the reasons for not making the amendment(s) requested.

§21.75 Rights of legal guardians.

For the purposes of this part, the parent of any individual who is a minor or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction may act on behalf of the individual.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart A—General Provisions

Sec.

25.1 Purpose.

25.5 Terminology.

25.10 Policies and NEPA planning.

Subpart B—Agency Actions Requiring Environmental Consideration

25.15 General procedures.

25.16 Public health and safety emergencies.

25.20 Actions requiring preparation of an environmental assessment.

25.21 Extraordinary circumstances.

25.22 Actions requiring the preparation of an environmental impact statement.

Subpart C—Categorical Exclusions

25.30 General.

25.31 Human drugs and biologics.

25.32 Foods, food additives, and color additives.

25.33 Animal drugs.

25.34 Devices and electronic products.

Subpart D—Preparation of Environmental Documents

25.40 Environmental assessments.

25.41 Findings of no significant impact.

25.42 Environmental impact statements.

25.43 Records of decision.

25.44 Lead and cooperating agencies.

25.45 Responsible agency official.

Subpart E—Public Participation and Notification of Environmental Documents

25.50 General information.

25.51 Environmental assessments and findings of no significant impact.

25.52 Environmental impact statements.

Subpart F—Other Requirements

25.60 Environmental effects abroad of major

agency actions.

AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500-1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531-533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123-124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356-360.

SOURCE: 62 FR 40592, July 29, 1997, unless otherwise noted.

Subpart A—General Provisions

§25.1 Purpose.

The National Environmental Policy Act of 1969 (NEPA), as amended, directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements. The regulations in this part implement section 102(2) of NEPA in a manner that is consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This part also supplements the regulations for implementing the procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508 and the procedures included in the "HHS General Administration Manual, part 30: Environmental Protection" (45 FR 76519 to 76534, November 19, 1980).

§25.5 Terminology.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR part 1508. The terms and the sections of 40 CFR part 1508 in which they are defined follow:

(1) Categorical exclusion (40 CFR 1508.4).

(2) Cooperating agency (40 CFR 1508.5).

(3) Cumulative impact (40 CFR 1508.7).

(4) Effects (40 CFR 1508.8).

(5) Environmental assessment (EA) (40 CFR 1508.9).